REMARKS

In view of the foregoing amendments and the following representations, reconsideration and allowance of the above-identified application is respectfully requested.

Claims 1-4, 7-14, 17-20 and 31-34 are pending in the present application.

35 U.S.C. § 112

On page 3 of the Office Action, the Examiner rejected claims 1-4, 7-14, 17-24 and 27-31 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner rejected the claims based upon the use of the term "isomers or derivatives". Although Applicants believe the term "isomer or derivatives" is definite for the reasons of record, Applicants have amended independent claims, 1, 11 and 31 to indicate that the "thiazolidinedione derivative" is pioglitazone or pharmaceutically acceptable salts thereof. Applicants have also amended claim 18 to correct a typographical error. No new matter is added by these amendments. Support can be found in the claims as originally filed and Examples 1-6 of the present specification.

Based upon the foregoing amendments, it is respectfully requested that the rejection of the claims under 35 U.S.C. § 112, second paragraph, be withdrawn.

35 U.S.C. § 103(a)

On pages 4-5 of the Office Action, the Examiner rejected claims 1-31 under 35 U.S.C. § 103(a) as being unpatentable over the teachings of Vergez et al., United States Published Patent Application No. 2006/0204578 ("Vergez").

In response to this rejection, Applicants have amended the claims to specifically indicate that the claimed dosage form requires controlled release of the metformin and immediate release of the pioglitazone. Specifically, each claim requires that the dosage form release 10-45% of the metformin within 4 hours, 30-90% of the metformin within 8 hours and not less than 75% of the pioglitazone within 30 minutes of *in vitro* dissolution testing. Applicants have also added new claims 32-34. New claim 32, depends on claim 1 and incorporates the limitations of canceled claim 21. New claims 33 and 34 also depend on claim 1 and incorporate additional in vitro dissolution parameters for the dosage form. No new matter is added by the present amendments. Support can be found on page 11, lines 7-27 and page 25, lines 5-15 of the specification for the dissolution limitations and original claim 21 for the elements of new claim 32.

It is respectfully submitted that present amendments requiring controlled release of the metformin and immediate release of the pioglitazone renders the present claims patentable over the Vergez reference which requires controlled release of two active ingredients. See: Vergez, ¶ 2 ("This invention pertains to a dosage form that provides a controlled release of two different drugs."); ¶ 15 ("The present invention provides an oral dosage form that provides a controlled release device of two or more different agents"); ¶ 70 ("Neither one of the compositions in the core is intended for rapid release of active

agent"); and ¶ 73 ("Neither of the first or second active agents is released rapidly from the core").

Applicants respectfully submit that the very broad and general teachings of the Vergez reference do not render obvious the pending claims. The presently amended claims recite a dosage form that comprises a controlled release metformin core, a rapidly dissolving or dispersible primary seal coat and an immediate release pioglitazone coat applied to the primary seal coat. The controlled release core can be any type of controlled release core such as a hydrogel matrix or osmotic tablet but it can contain only one pharmaceutically active ingredient, specifically metformin. Futher, the metformin is the only active ingredient released in a controlled manner. The second active ingredient, pioglitazone is released immediately. The controlled release of only metformin and immediate release of the pioglitazone is confirmed by the inclusion of the metformin and pioglitazone dissolution profiles in the independent claims. The controlled release of metformin and immediate release of pioglitazone is further confirmed by claims 10, 20 and 31 which require the *in vivo* time to maximum pioglitazone plasma concentration (Tmax) for the dosage form to be 1-4 hours.

The controlled release of only metformin and immediate release of pioglitazone is contrary to the teachings of the Vergez reference. The Vergez reference requires the controlled release of two active ingredients. There is no suggestion or guidance in the Vergez reference that would lead an individual of ordinary skill to develop a once a day metformin/pioglitazone dosage form as recited in the pending claims. In addition, there is no suggestion or motivation to develop a controlled release metformin core, coat it with

a drug free rapidly disintegrating or dispersing primary seal coat and apply an immediate release pioglitazone layer to the primary seal coat based a broad general teaching of the Vergez.

As explained in the prior submission, it was only after much research and experimentation that Applicants arrived at the particular arrangement of a controlled release metformin core/rapidly water soluble or dispersible primary seal coat/immediate release pioglitazone layer. This arrangement for a once a day product could not have been predicted or rendered obvious in view of the vastly different solubility and stability issues for metformin and pioglitazone. The Vergez reference does not provide any guidance for accommodating the different solubility and stability profiles of metformin and pioglitazone in a single dosage form.

Based upon the foregoing amendments and representations, it is respectfully submitted that the pending claims are patentable over the Vergez reference because the pending claims require a controlled release metformin core and an immediate release pioglitazone coating applied to a rapidly dissolving or disintegrating primary seal coat. This unique metformin/pioglitazone dosage form is not suggested or disclosed by the Vergez reference which teaches a controlled release core with two different active ingredients in the core and a broad general disclosure of the possibility of an immediate release layer.

DOUBLE PATENTING

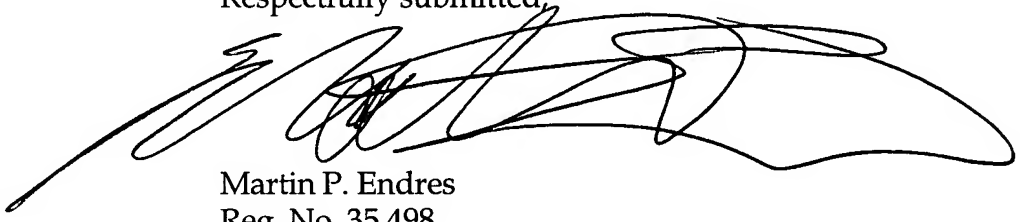
On pages 2-3 of the Office Action, the Examiner maintained the provisional non-statutory obviousness-type double patenting rejection in view of claims 1, 2, 4 and 8-10 of co-pending United States Patent Application No. 11/094,493.

Based upon the present amendments, it is believed that this provisional double patenting rejection should be the only rejection remaining in the present application. Because the present application was filed before United States Patent Application 11/094,493 and 11/094,493 is currently rejected under 35 U.S.C. §§ 103 and 112, first paragraph, it is respectfully submitted that the provisional double patenting rejection of the present application be withdrawn and a notice of allowance issued. The withdrawal of the provisional double patenting rejection is appropriate according to MPEP § 804(I)(B)(1) which reads in relevant part as follows:

> If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier filed application to issue as a patent without a terminal disclaimer.

Based upon the foregoing amendments and representations, Applicants respectfully requested that the rejection of the claims in the above-identified application be withdrawn. Early and favorable action is earnestly solicited.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 on Jan. 4, 2008

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